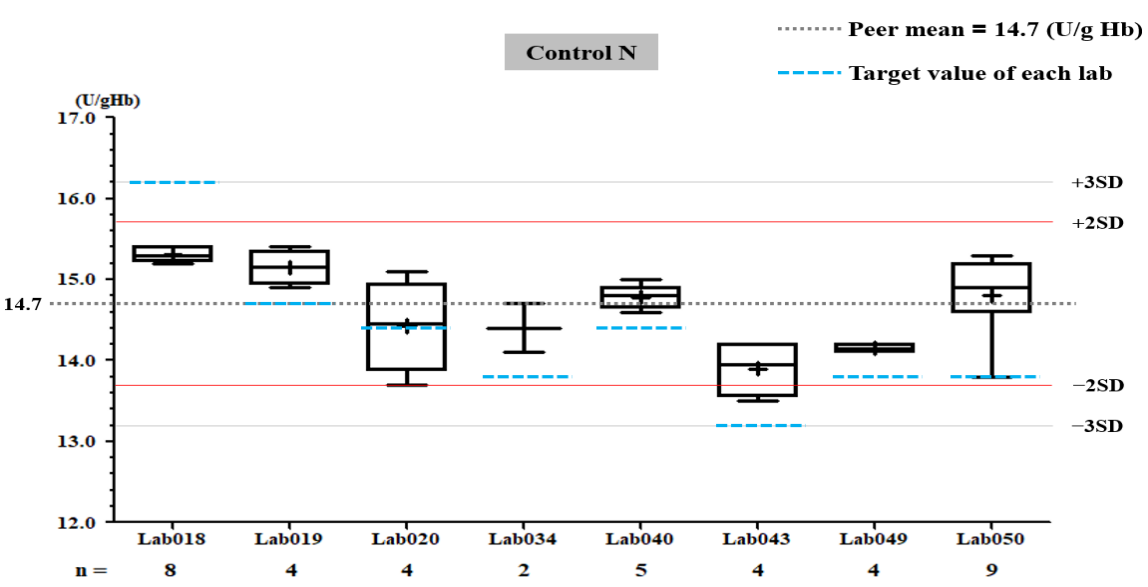
Summary Report of IQC program for G6PD Quantitative Test - Medicon Group - June 2024 -

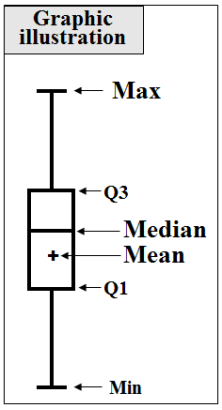
I. The statistic results of all laboratories in this month

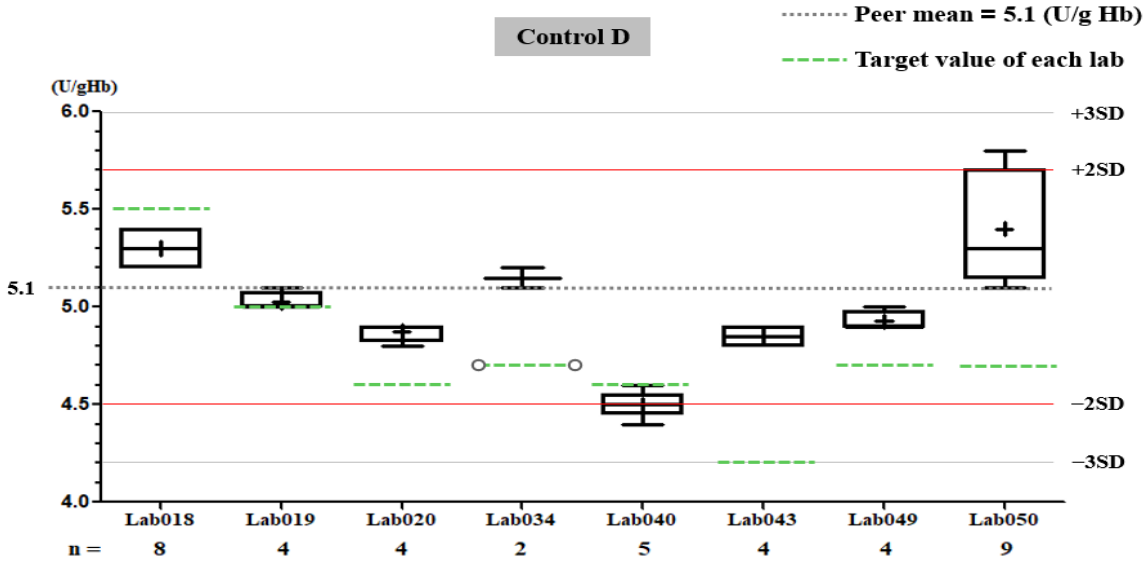
G6PD	Control N (Lot No.:BJ0922N)	Control D (Lot No.: BJ0922D)
Labs	8	8
Received results number (n)	40	40
Median	14.8 (U/g Hb)	5.1 (U/g Hb)
Mean	14.7 (U/g Hb)	5.1 (U/g Hb)
SD	0.5	0.3
CV	3.4%	5.9%
Range of G6PD	13.5 ~ 15.4 (U/g Hb)	4.4 ~ 5.8 (U/g Hb)
Range of Hb	1.9 ~ 2.6 (g/dL)	1.7 ~ 2.2 (g/dL)

*The statistic results are calculated from all labs reported in this month
** G6PD Method = Medicon reagent kit, 37°C

II. The distribution of G6PD reported for each lab in this survey







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QC Chart of Internal Quality Control (IQC)for G6PD Quantitative Test

Select LotNo： BJ0922N (2021-01-01 ~ 2100-12-31) Change

Print Table

Lab040

	Control N		Control D	
QC Control Lot No.	BJ0922N		BJ0922D	
Duration of the Analyzing	Month (2024/06)	CUM (2024/02/02~2024/06/30)	Month (2024/06)	CUM (2024/02/02~2024/06/30)
Runs (N)	5	26	5	26
Mean (U/gHb)	14.8	14.7	4.5	4.6
SD	0.2	0.2	0.1	0.1
CV (%)	1.4	1.4	2.2	2.2
Target Value (U/gHb)	14.4	14.4	4.6	4.6
Total Error (%)	5.5	4.8	6.6	4.3
TEa (%)	20	20	20	20
σ	>6	>6	>6	>6

Bias (%) = [(\| Mean - Target \|) / Target] x 100%
TE：Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 06 Change ; Cumulative : from 2024 02 02 to 2024 06 30 Change

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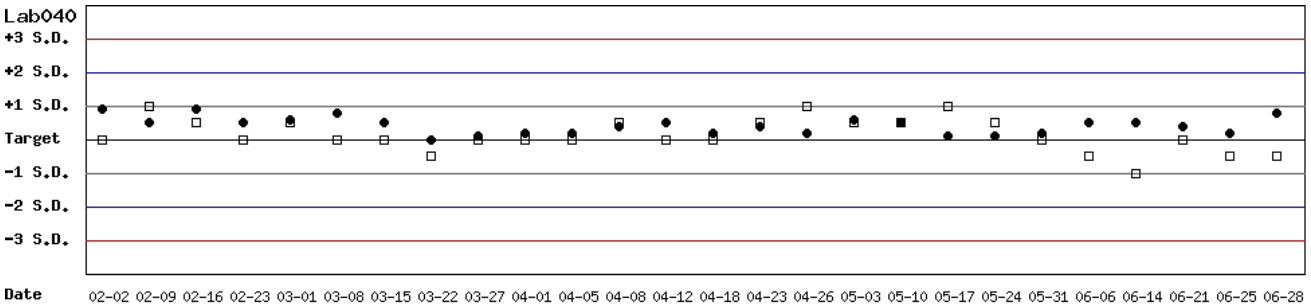
Control N and Control D SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-02-02 to 2024-06-30 ; Target : 14.4 ; SD : 0.80 (●)

Lot No.: BJ0922D ; Duration : 2024-02-02 to 2024-06-30 ; Target : 4.6 ; SD : 0.20 (□)

Lab040



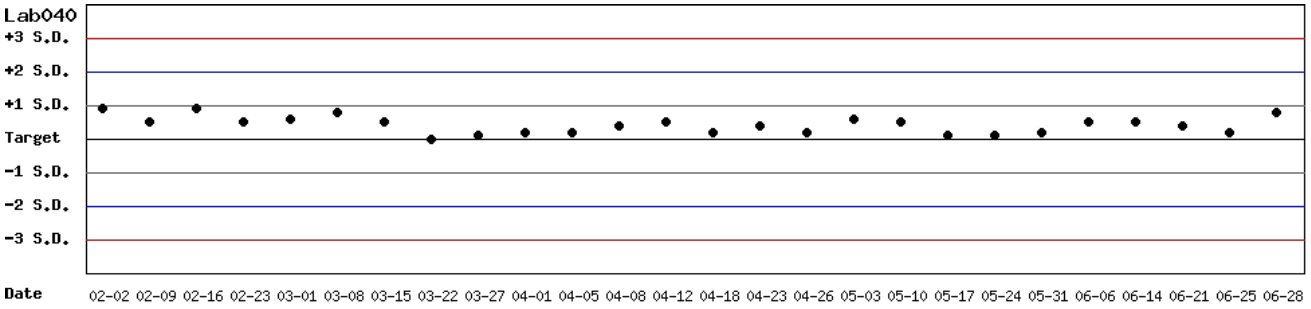
Month : 2024 06 Change ; Cumulative : from 2024 02 02 to 2024 06 30 Change

[TOP]

Control N SDI QC Chart

Lot No.: BJ0922N ; Duration : 2024-02-02 to 2024-06-30 ; Target : 14.4 ; SD : 0.80

Lab040



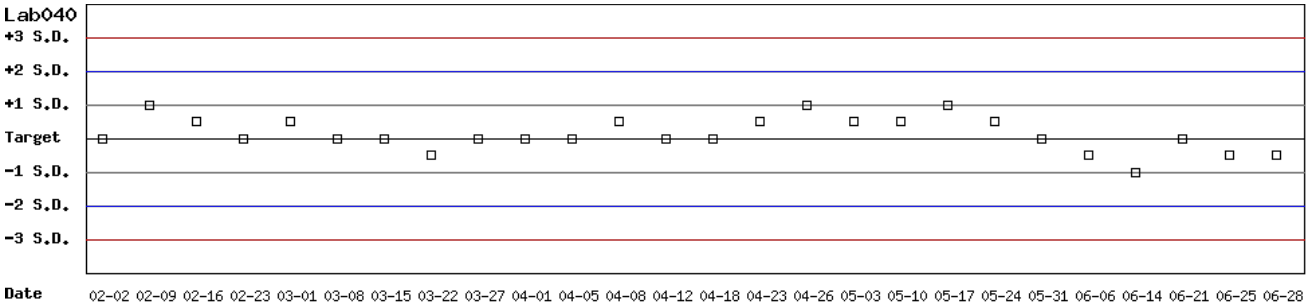
Month : 2024 06 Change ; Cumulative : from 2024 02 02 to 2024 06 30 Change

[TOP]

Control D SDI QC Chart

Lot No.: BJ0922D ; Duration : 2024-02-02 to 2024-06-30 ; Target : 4.6 ; SD : 0.20

Lab040



Month : 2024 06 Change ; Cumulative : from 2024 02 02 to 2024 06 30 Change

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Peer Group Statistics (Table 1)

Select LotNo： BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit： 5 - Medicon Change

Print Table 1

Monthly

Month : 2024 06 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab018	5	16.2	15.3	8	0.1	0.7	6.9	20	>6	5.5	5.3	8	0.1	1.9	7.4	20	>6
Lab019	5	14.7	15.2	4	0.2	1.3	6.0	20	>6	5.0	5.0	4	0.1	2.0	4.0	20	>6
Lab020	5	14.4	14.4	4	0.6	4.2	8.3	20	4.8	4.6	4.9	4	0.1	2.0	10.6	20	>6
Lab034	5	13.8	14.4	2	-	-	-	20	-	4.7	5.2	2	-	-	-	20	-
Lab040	5	14.4	14.8	5	0.2	1.4	5.5	20	>6	4.6	4.5	5	0.1	2.2	6.6	20	>6
Lab043	5	13.2	13.9	4	0.4	2.9	11.1	20	5.1	4.2	4.9	4	0.1	2.0	20.7	20	1.7
Lab049	5	13.8	14.2	4	0.1	0.7	4.3	20	>6	4.7	4.9	4	0.1	2.0	8.3	20	>6
Lab050	5	13.8	14.8	9	0.5	3.4	14.0	20	3.8	4.7	5.4	9	0.3	5.6	26.0	20	0.9
Total	-	-	14.7	40	0.5	3.4	-	-	-	-	5.1	40	0.3	5.9	-	-	-

Bias (%) = [(\| Mean - Target \|) / Target] x 100%
TE： Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

[TOP]

Cumulative

Cumulative : from 2021 01 01 to 2024 06 30 Change

		Control N (Lot No.: BJ0922N)								Control D (Lot No.: BJ0922D)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab018	5	16.2	15.3	86	0.4	2.6	10.8	20	5.6	5.5	5.4	86	0.1	1.9	5.5	20	>6
Lab019	5	14.7	14.5	118	0.6	4.1	9.6	20	4.5	5.0	4.8	118	0.3	6.3	16.5	20	2.5
Lab020	5	14.4	14.4	89	0.5	3.5	6.9	20	5.7	4.6	4.7	89	0.2	4.3	10.7	20	4.1
Lab022	5	14.4	14.4	27	0.5	3.5	6.9	20	5.7	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	15.2	15.1	34	1.1	7.3	15.2	20	2.6	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	14.9	14.3	153	0.4	2.8	9.6	20	5.7	4.8	4.5	153	0.2	4.4	15.1	20	3.1
Lab033	5	13.8	13.6	81	0.7	5.1	11.7	20	3.6	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab034	5	13.8	14.4	11	0.4	2.8	9.9	20	5.6	4.7	5.2	11	0.2	3.8	18.3	20	2.5
Lab037	5	13.8	14.5	59	0.5	3.4	12.0	20	4.4	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	14.4	14.8	114	0.2	1.4	5.5	20	>6	4.6	4.6	114	0.1	2.2	4.3	20	>6
Lab043	5	13.2	13.9	145	1.1	7.9	21.1	20	1.9	4.2	4.6	145	0.4	8.7	26.9	20	1.2
Lab049	5	13.8	14.4	215	0.6	4.2	12.7	20	3.7	4.7	4.7	215	0.3	6.4	12.8	20	3.1
Lab050	5	13.8	14.5	29	0.6	4.1	13.3	20	3.6	4.7	5.3	29	0.3	5.7	24.1	20	1.3
Total	-	-	14.4	1161	0.7	4.9	-	-	-	-	4.7	1161	0.3	6.4	-	-	-

Bias (%) = [(\| Mean - Target \|) / Target] x 100%
TE： Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

[TOP]

Reagent Kit	Reagent Code
Medicon	5

Peer Group Statistics (Table 2)

Select LotNo： BJ0922N (2021-01-01 ~ 2100-12-31) Change

Select Reagent Kit： 5 - Medicon Change

Print Table 2

Control N Month vs. Cumulative

		Control N (Lot No.: BJ0922N)															
		Month (2024/06)								CUM (2021/01/01~2024/06/30)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab018	5	16.2	15.3	8	0.1	0.7	6.9	20	>6	16.2	15.3	86	0.4	2.6	10.8	20	5.6
Lab019	5	14.7	15.2	4	0.2	1.3	6.0	20	>6	14.7	14.5	118	0.6	4.1	9.6	20	4.5
Lab020	5	14.4	14.4	4	0.6	4.2	8.3	20	4.8	14.4	14.4	89	0.5	3.5	6.9	20	5.7
Lab022	5	14.4	-	0	-	-	-	20	-	14.4	14.4	27	0.5	3.5	6.9	20	5.7
Lab028	5	15.2	-	0	-	-	-	20	-	15.2	15.1	34	1.1	7.3	15.2	20	2.6
Lab032	5	14.9	-	0	-	-	-	20	-	14.9	14.3	153	0.4	2.8	9.6	20	5.7
Lab033	5	13.8	-	0	-	-	-	20	-	13.8	13.6	81	0.7	5.1	11.7	20	3.6
Lab034	5	13.8	14.4	2	-	-	-	20	-	13.8	14.4	11	0.4	2.8	9.9	20	5.6
Lab037	5	13.8	-	0	-	-	-	20	-	13.8	14.5	59	0.5	3.4	12.0	20	4.4
Lab040	5	14.4	14.8	5	0.2	1.4	5.5	20	>6	14.4	14.8	114	0.2	1.4	5.5	20	>6
Lab043	5	13.2	13.9	4	0.4	2.9	11.1	20	5.1	13.2	13.9	145	1.1	7.9	21.1	20	1.9
Lab049	5	13.8	14.2	4	0.1	0.7	4.3	20	>6	13.8	14.4	215	0.6	4.2	12.7	20	3.7
Lab050	5	13.8	14.8	9	0.5	3.4	14.0	20	3.8	13.8	14.5	29	0.6	4.1	13.3	20	3.6
Total	-	-	14.7	40	0.5	3.4	-	-	-	-	14.4	1161	0.7	4.9	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE： Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 06 Change Cumulative : from 2021 01 01 to 2024 06 30 Change

[TOP]

Control D Month vs. Cumulative

		Control D (Lot No.: BJ0922D)															
		Month (2024/06)								CUM (2021/01/01~2024/06/30)							
UnitID	Reagent Kit (Code)	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ	Target (U/gHb)	Mean (U/gHb)	n for Mean	SD	CV (%)	TE (%)	TEa (%)	σ
Lab018	5	5.5	5.3	8	0.1	1.9	7.4	20	>6	5.5	5.4	86	0.1	1.9	5.5	20	>6
Lab019	5	5.0	5.0	4	0.1	2.0	4.0	20	>6	5.0	4.8	118	0.3	6.3	16.5	20	2.5
Lab020	5	4.6	4.9	4	0.1	2.0	10.6	20	>6	4.6	4.7	89	0.2	4.3	10.7	20	4.1
Lab022	5	4.6	-	0	-	-	-	20	-	4.6	4.7	27	0.3	6.4	14.9	20	2.8
Lab028	5	4.9	-	0	-	-	-	20	-	4.9	4.9	34	0.3	6.1	12.2	20	3.3
Lab032	5	4.8	-	0	-	-	-	20	-	4.8	4.5	153	0.2	4.4	15.1	20	3.1
Lab033	5	4.7	-	0	-	-	-	20	-	4.7	4.6	81	0.3	6.5	15.2	20	2.7
Lab034	5	4.7	5.2	2	-	-	-	20	-	4.7	5.2	11	0.2	3.8	18.3	20	2.5
Lab037	5	4.7	-	0	-	-	-	20	-	4.7	4.7	59	0.2	4.3	8.5	20	4.7
Lab040	5	4.6	4.5	5	0.1	2.2	6.6	20	>6	4.6	4.6	114	0.1	2.2	4.3	20	>6
Lab043	5	4.2	4.9	4	0.1	2.0	20.7	20	1.7	4.2	4.6	145	0.4	8.7	26.9	20	1.2
Lab049	5	4.7	4.9	4	0.1	2.0	8.3	20	>6	4.7	4.7	215	0.3	6.4	12.8	20	3.1
Lab050	5	4.7	5.4	9	0.3	5.6	26.0	20	0.9	4.7	5.3	29	0.3	5.7	24.1	20	1.3
Total	-	-	5.1	40	0.3	5.9	-	-	-	-	4.7	1161	0.3	6.4	-	-	-

Bias (%) = [(| Mean - Target |) / Target] x 100%
TE： Total Error(%) = Bias (%) + 2 × CV (%)
σ (Sigma) = [TEa% - Bias (%)] / CV (%)

Month : 2024 06 Change Cumulative : from 2021 01 01 to 2024 06 30 Change

[TOP]

Reagent Kit	Reagent Code
Medicon	5